

VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Laetitia Cousin

AUG - 8 2007

Director of Regulatory Affairs and Quality Assurance

NuVasive, Incorporated 4545 Towne Centre Court San Diego, California 92121 Telephone: (858) 909-1868

Fax: (858) 909-2068

B. Device Name

Trade or Proprietary Name:

NuVasive HELIX ACP System

Common or Usual Name:

Cervical Plate and Screw System

Classification Name:

Spinal Intervertebral Body Fixation Orthosis

Device Class: Classification: Class II §888.3060

Product Code:

KWQ

C. Predicate Devices

The subject *HELIX ACP System* is substantially equivalent to the *Gradient Plus System* currently distributed commercially in the U.S. by NuVasive.

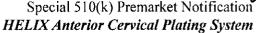
D. Device Description

The NuVasive HELIX ACP System consists of a variety of plates and screws designed to provide stabilization as an adjunct to cervical fusion.

E. Intended Use

The NuVasive HELIX ACP System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive HELIX ACP System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.





Comparison to Predicate Devices F.

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation.

G. **Summary of Non-Clinical Tests**

Mechanical testing was presented.

H. **Summary of Clinical Tests**

(Not Applicable).



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

AUG - 8 2007

NuVasive, Incorporated % Ms. Laetitia Cousin Director of Regulatory Affairs, Clinical Affairs and Quality Assurance 4545 Towne Centre Court San Diego, California 92121

Re: K071329

Trade/Device Name: NuVasive HELIX ACP System

Regulation Number: 21 CFR 888.3060

Regulation Name: Spinal intervertebral body fixation orthosis

Regulatory Class: Class II Product Code: KWQ Dated: July 20, 2007 Received: July 23, 2007

Dear Ms. Cousin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

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Indications for Use

Vn71379

510(k) Number (if known):
Device Name: HELIX Anterior Cervical Plating System
Indications For Use:
The NuVasive HELIX Anterior Cervical Plating System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.
WARNING: The NuVasive HELIX Anterior Cervical Plating System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)

(Division Sign-Off) Division of General, Restorative,

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and Neurological Devices

510(k) Number <u>K07/329</u>